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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|--------------------------|---------------------|------------------|
| 09/291,347      | 04/14/1999  | JULIAN ALEXIS JOHN HANAK | CACO-0051           | 1979             |

7590 11/28/2001

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EXAMINER

TUNG, PETER P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED: 11/28/2001

16

Please find below and/or attached an Office communication concerning this application or proceeding.

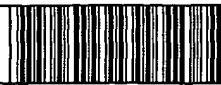
# Office Action Summary

Application No.  
**09/291,347**

Applicant(s)  
**Hanak et al.**

Examiner  
**Peter Tung**

Art Unit  
**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 25, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 36 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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### **DETAILED ACTION**

1. Claims 1-18 and 36 are pending.
2. Based upon the new grounds of rejection, the finality of the previous Office action is hereby withdrawn.

#### ***Claim Objections***

3. Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This objection is explained in the previous Office action.
4. Applicants argue that claim 1 does not specify that the cells which produce the cellular component also produce the RNase and that it is only specified that the cell lysate contains both the cellular component and the RNase.
5. Applicant's arguments filed 6/25/01 have been fully considered but they are not persuasive. While claim 1 may not explicitly specify that the cells which produce the cellular component also produce the RNase, claiming that the cell lysate contains both the cellular component and the RNase inherently implies that the cells cultured in the medium contain both cellular component and the RNase.

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***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the instant method wherein the RNase is secreted into the periplasm of the cell, does not reasonably provide enablement for secretion out of the cytoplasm or out of the cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. As secretion of the RNase into a space other than the periplasm would result in dilution of the RNase, the RNase activity would be lost such that there would not be sufficient RNase activity to degrade substantially all of the RNA molecules present. Insufficient guidance and examples have been provided on the method where the RNase is secreted to other than the periplasmic space. The relative skill of those in the art is low without such guidance or examples. Undue experimentation would be required to enable the full scope of the invention based upon the instant disclosure.

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8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-18 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 1-18 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: following the lysis of the cells, incubation of the lysate to allow the RNase to digest the RNA molecules.

11. Claim 7 is unclear as to what the cellular component is one of. The claim appears to be an improper Markush claim for members of the group consisting of recombinant DNA, protein, and carbohydrate.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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13. Claims 1-5, 7-12, 14, 18 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Meador et al. (Gene, 1990). Meador et al. teach (page 3, first column, next to last paragraph to page 3, 2nd column, last paragraph) a method of isolating an RNase comprising culturing cells, isolating a spheroplast fraction, lysing the spheroplasts such that the lysate contained a sufficient amount of RNase to degrade the RNA molecules and isolating the RNase O. RNase O is encoded by genomic DNA. Meador et al. further state that the bacterial strains had “enormously elevated levels of a nonspecific endonuclease,” referring to RNase O. As the cellular lysate contains a sufficient amount of RNase to degrade substantially all of the RNA molecules present, the instant claims are therefore anticipated by Meador et al. It is noted that the claim limitation of “sufficient RNase activity to degrade substantially all of the RNA molecules present” only identifies that there is RNase activity present. As enzymes are catalysts, any reasonable amount of RNase activity would be sufficient to degrade all of the RNA molecules present in the cell lysate.

14. Claims 1-5, 7-11, 14, 18 and 36 are rejected in the alternative under 35 U.S.C. 102(b) as being anticipated by Sambrook et al. Sambrook et al. teach (page 1.34, “Harvesting”; pages 1.38 and 1.39, “Lysis by alkali”) the isolation of a recombinant plasmid by culturing cells, harvesting the cells, lysing the cells by alkali, and isolating the plasmid DNA, which is that of the instant claims. As the cellular lysate contains a sufficient amount of RNase to degrade substantially all of the RNA molecules present, the instant claims are therefore anticipated by Sambrook et al. It is noted that the claim limitation of “sufficient RNase activity to degrade substantially all of the RNA molecules present” only identifies that there is RNase activity present. As enzymes are

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catalysts, any reasonable amount of RNase activity would be sufficient to degrade all of the RNA molecules present in the cell lysate.


15. Applicant's arguments with respect to claims 1-18 and 36 have been considered but are moot in view of the new ground(s) of rejection.

*Conclusion*

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
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SUPERVISORY PATENT EXAMINER  
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